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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,684	10/25/2001	David P. Katz	AMBIINC.006A	3175

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EXAMINER	
PATTEN, PATRICIA A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,684	KATZ, DAVID P.	
	Examiner	Art Unit	
	Patricia A Patten	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1 136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *21-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-25 are pending in the application.

Newly submitted claims 21-25 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 21-25 are drawn to a method of treating PCOS comprising administration of synthetic chromium complex while the claims originally presented were drawn to the method for treating PCOS comprising administration of a chromium complex. The methods of are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone. The search for each of the above inventions is not co-extensive *particularly with regard to the literature search*. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Because these inventions are distinct for the reasons given above and the search required for each Group is not required for the others, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-25 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Arguments solely drawn to the rejection under 35 U.S.C. 103(a) in view of Ostlund et al. (claim 1) are moot considering this rejection has been removed

Claims 1-20 were examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-20 either recite, or depend upon a claim which recites 'consisting essentially of'. This phrase is indefinite because Applicant has not defined 'consisting essentially of.' This statement is confusing in that it is taught in the Instant specification as well as the claims that other pharmacologically active ingredients may be added to the composition for treating PCOS. Therefore, the metes and bounds of the phrase

"consisting essentially of' are unclear. Because of this ambiguity, the Examiner has interpreted 'consisting essentially of' to mean 'comprising' and the claims will be examined on the merits as such.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 remain rejected and claims 16-20 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over de la Harpe et al. (US 5,980,905) in view of Ostlund et al. (US 5,550,166). New claims 16-20 are drawn to a method for treating PCOS via administration of a composition consisting essentially of at least one chromium-containing compound. Because these claims were interpreted to mean 'comprising', new claims 16-20 are drawn to essentially the same subject matter of claims 1-5, the claims are found obvious under this statute for the same reasoning as set forth in the previous Office Action for claims 1-5.

Applicant's arguments were fully considered, but not found persuasive.

Applicant argues that this rejection is insufficient, as Applicant contends that Ostlund et al. taught that pinitol was used for treating conditions of insulin resistance and de la Harpe et al. did not specifically teach wherein chromium compounds such as chromium picolinate treated insulin resistance.

The Examiner respectfully disagrees for the following reasons:

De la Harpe et al. clearly taught that dietary supplementation of chromium to normal individuals had been reportedly linked to improvements in "...glucose tolerance, serum lipid concentrations, including high density lipoprotein cholesterol, insulin and ***insulin binding***..." (Emphasis added)(col.1, lines 45-48). Further, de la Harpe et al. indicate that "Chromium functions as a cofactor for insulin. It binds to the insulin receptor and potentiates many, and perhaps all, of its functions" (col.1, lines 54-56). Thus, *chromium acts in alleviating insulin resistance*. It is further noted that Applicants have amended the claims to read 'chromium compound'. While this is indeed interpreted as a different substance than a 'chromium complex', it is made clear in de la Harpe et al. that it is the chromium which is the active ingredient. De la Harpe et al noted that "Chromium....must be consumed as a biologically active molecule". Therefore, it is deemed that the administration of chromium, weather as a compound

such as chromium picolinate or chromium yeast would have essentially the same function: delivery of the active chromium.

It is made clear in the Instant specification that 'method for treating polycystic ovary syndrome' means that the patient having PCOS is treated for insulin related complications (the claims are read in light of the specification) and not all etiologies of the disease. This is especially evident considering that the only working examples present in the Instant specification demonstrate a decrease in body mass and improved lipid profile. It is further apparent that the Instant specification does not suggest the use of chromium compounds for any other symptoms of PCOS.

The ordinary artisan would have recognized that because one of the symptoms of PCOS is diabetes-2 characterized by insulin resistance as well as hyperglycemia, that chromium, which was known in the art to function as a cofactor for insulin, i.e., potentiating functions such as carbohydrate metabolism, would have been beneficial in treating diabetes and diabetes symptoms associated with PCOS. Thus, the results found within the Instant specification *would have been expected* taking de la Harpe et al. in view of Ostlund et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. The official After final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

July 1, 2003

Patricia Patten

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600